K040680

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JUN 1 4 2004

510(K) SUMMARY

CONTOUR HA COATED RECONSTRUCTION RING

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6670
CONTACT PERSON:	John Reabe
DATE SUMMARY PREPARED:	March 8, 2004
TRADE OR PROPRIETARY DEVICE NAME:	Contour HA Coated Reconstruction Ring
COMMON OR USUAL NAME:	Surgical Mesh
CLASSIFICATION NAME:	Surgical Mesh
DEVICE CLASS:	Class II
PANEL CODE:	General and Plastic Surgery/79

DEVICE INFORMATION:

INTENDED USE:
Total hip components are indicated for individuals undergoing primary or revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis; or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip and correction of deformity.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously. The device is intended for single use.

DEVICE DESCRIPTION:
The Contour HA Coated Reconstruction Ring features a partial cup shape, multiple screw holes and three flanges. The reconstruction ring is secured to host bone or graft bone with bone screws. A Reflection All Poly Cup may be cemented in the reconstruction ring with polymethylmethacrylate (PMMA) bone cement.

SUBSTANTIAL EQUIVALENCE INFORMATION:
The Contour HA Coated Reconstruction Ring is substantially equivalent to the Smith & Nephew Reflection Acetabular Reinforcement Rings (K962541), Osteonics Restoration Acetabular Ring (K970957), and DePuy Protrusio Cage (K962007). The Contour HA Coated Reconstruction Ring has a HA coating that is substantially equivalent to the HA coating on the Smith & Nephew HA Ti-Fit Femoral and Acetabular Components (K922621) and the Smith & Nephew InterFit HA Coated Acetabular Shell (K990666).

SUMMARY OF TECHNOLOGICAL COMPARISON:
The Contour HA Coated Reconstruction Ring is substantially equivalent to the predicate devices listed in the previous section in terms of material, indications for use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2004

John Reabe
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K040680
Trade/Device Name: Contour HA Coated Reconstruction Ring
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: MEH
Dated: March 10, 2004
Received: March 16, 2004

Dear Mr. Reabe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) number (if known): K040680

Device Name: Contour HA Coated Reconstruction Ring

Indications for Use:

Total hip components are indicated for individuals undergoing primary or revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis; or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip and correction of deformity.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040680